Draft Minutes of Diacetyl/Flavoring Advisory Meeting
DOSH Oakland Training room 1304
July 10, 2007

Attendees:

NAME	AFFILIATION
Aho, Janet	Mane, Inc.
Ali, Zohra	DOSH Compliance
Brown, Jay	Dean Distributors, Inc.
Broyles, Juli	GMA/FPA
D'Amato, Bob	American Safety Institute
Edens, Amanda	Federal OSHA
Falasco, Mike	Wine Institute
Freyman, Judi	ORC Worldwide
Fuller, Julie MD	UCI Occ. Med. Resident
Graham, Diana	KH Law
Hallagan, John	FEMA
Hogan, Mary Ellen	Holme Roberts&Owen,LLP
Hrabchak, Rhonda	American Fruits&Flavors
Kochie, Mary	Cal/OSHA
Kreiss, Kay	NIOSH
Leiner, Dan	Cal/OSHA Consultation
Luke, Marilyn	Federal OSHA
Mashayekhi, Azita	Teamsters
Materna, Barbara	OccHealth, CA DHS
McKernan, Lauralynn	NIOSH
Pulliam, Michael	Drinker, Biddle &Reath
Rabinowitz, Bobbie	Worksafe
Rachman, Nancy	GMA/FPA
Riley, Peter	DOSH Compliance Mgr.
Roberts, Jennifer	health scientist ChemRisk
Schreiberg, Fran	Worksafe
Scott, Mark	T.Hasegawa USA
Smith, Jeremy	CA Labor Federation
Wade, Erin	Littler Mendelson, PC
Wasser, Neil	Constangy,Brooks&SmithLLC
Len Welsh	DOSH Acting Chief
Steve Smith	DOSH Research & Standards Unit
Bob Barish	DOSH Research & Standards Unit
Mike Horowitz	DOSH Research & Standards Unit
Tom Mitchell	Cal/OSHA Standards Board

OPENING OF THE MEETING

Len Welsh gave a review of the Cal/OSHA advisory process and the status of this series of pre-rulemaking meetings on diacetyl and flavorings. Len Welsh said this fifth meeting

was significant because he believed it would be the last before a proposed rule would be sent by the Division to the Cal/OSHA Standards Board. The public input up to this point had been part of an informal process. After the Board staff analyzes the Division's proposal and supporting documents, the Board will initiate the formal rulemaking process by publishing a 45-Day Notice soliciting official comment, Welsh explained. At the end of this period the Board will hold a public hearing to receive additional written or oral comments. If, as a result of the received comments, changes to the proposal are needed in the view of the Board, one or more 15-Day comment periods will be established for the public to comment on the proposed changes to the original proposal, Welsh said.

Len Welsh noted that Federal OSHA is affected by a proposed Congressional bill calling for emergency temporary and permanent standards on diacetyl. If a Federal rule on diacetyl is created, Welsh said, this could require changes to any California rule that has been adopted. California has a small flavor industry of about 28 companies that sell compounded flavors to a much larger food manufacturing industry, Welsh said. He predicted that most of today's meeting would probably focus on the food manufacturing industry.

He noted how studying exposures to diacetyl in the flavoring and food manufacturing industries in California posed unique challenges compared to the studies that had been done in the popcorn industry elsewhere in the nation. In the popcorn industry, application of diacetyl-containing flavorings was part of a steady-state operation and thus easy to study, while exposures in the flavoring industry and food manufacturing industries tended to be intermittent and logistically and scientifically difficult to study.

Len Welsh asked for progress reports on recent work on flavoring related issues, beginning with Cal/OSHA Consultation's efforts in the voluntary Flavoring Industry Safety and Health Emphasis Program (FISHEP)

SUMMARY OF RECENT FISHEP ACTIVITY

Cal/OSHA Consultation FISHEP coordinator Dan Leiner stated the program was working with 26 flavor manufacturing companies, while two other flavor manufacturers had been inspected by Cal/OSHA Enforcement. When the compliance issues for these two companies are settled, they will come under the FISHEP umbrella. FISHEP has been working with the California Department of Health Services (now called Department of Public Health) on medical issues and with NIOSH on engineering controls. FISHEP had found that the flavoring companies were either small or large diacetyl users. The smaller users were phasing out the use of diacetyl and substituting for its use. FISHEP has been working closely with these companies to develop better work practice controls. With two larger companies that have installed engineering controls, NIOSH and FISHEP are helping to evaluate the effectiveness of the new local exhaust ventilation. Two other flavoring manufacturers that are large users of diacetyl are in the plan/bid phase on local exhaust ventilation.

Leiner said that 90% of the FISHEP focus has been on air monitoring, including for other FEMA listed priority chemicals other than diacetyl. Scheduling such air monitoring has often been logistically difficult, as, especially for a few smaller users, use of the chemicals of interest is often infrequent, sometimes only once or twice a year. FISHEP is working on compiling the air monitoring data it has collected, including looking at Short Term Limit type monitoring [STEL, generally 15 minute samples] and partial shift monitoring. Besides diacetyl, FISHEP has monitored for acetic acid, benzaldehyde, ethyl acetate and other chemicals. Exposures to diacetyl have been found by FISHEP monitoring in flavor manufacturing plants.

FISHEP has begun to identify and inspect end user plants, having sampled in two at this time. One was a bakery where diacetyl was mixed into the product to be baked. The sampling result was non-detect.

Fran Schreiberg asked what the percentage of diacetyl was in that example. Dan Leiner said he would have to get that information. He said diacetyl use was in process of being phased out at this bakery, which was a Cal/OSHA Voluntary Protection Program member. FISHEP had also inspected a tortilla factory.

Leiner said that all the FISHEP companies have done the initial medical monitoring; FISHEP consultants were following up to ensure that the medical monitoring continued appropriately. FISHEP was also following up at the facilities to ensure that personal protective equipment and respirators were being used appropriately. Further sampling is being planned to verify the levels that were found due to new questions raised about the analytical method. [Humidity may have caused artificially low results,] FISHEP was pushing for the use of full face piece respirators although some companies were utilizing half face respirators. All affected employees have been quantitatively fit tested, however. Meanwhile, the Divisions Research and Education Consultation unit headed by Mario Felletto was developing training materials for FISHEP locations. Finally, all Cal/OSHA consultants have been instructed to ask about flavor and diacetyl use in any food manufacturing facility they inspect; if such use is identified, consultants are to contact FISHEP.

John Hallagan asked when the FISHEP process would end.

Len Welsh responded, stating that FISHEP was not a normal consultation. The end point will be when an employer has effectively implemented engineering controls, a sound respiratory protection program, adequate training and adequate medical screening. I don't think we are near the end point yet. Some company's still need engineering controls; we are still looking at another year yet for even the leaders of the pack. It might even take two years to follow up and assess engineering control effectiveness.

John Halligan offered assistance with any recalcitrant companies.

SUMMARY OF RECENT DHS/DPH ACTIVITY

Barbara Materna next summarized the continuing collection of the medical surveillance results on 474 workers who have had at least initial spirometry. Paul Enright, a NIOSH consultant, reviews all the pulmonary function tests (PFT) received. We have identified 26 workers with abnormal spirometry who need the next test, bronchodilation challenge. It is not likely that all of these 26 will prove to have obstructive lung disease. We have standardized communication with medical providers, including a system to notify providers and employers of the need for more tests. Along with physicians at NIOSH and National Jewish Hospital, we have developed a draft document to guide physicians with criteria for determining decreased lung function diagnosis via serial PFT. [Most providers are not used to looking for decreasing lung function as they traditionally use PFT as a pass/fail measure for respirator approvals.] This document calls for spirometry to be performed every six months and includes, in English and Spanish, questionnaires and a diacetyl fact sheet. The document will help physicians focus on early signs of disease and how to view serial spirometry to detect drops. [This is new for most providers, who are not used to looking for decreasing lung function. Traditionally they use PFT as a pass/fail measure for respirator approvals.] The remaining questions on the draft should be resolved in a conference call next week. Three more abnormal spirometry results have been added to the list since the last report to this group.

Len Welsh asked if these are restrictive, obstructive and fixed or unfixed PFT.

Barbara Materna replied that we won't know until the follow up bronchodilator challenge test is performed.

Len Welsh said that some think restrictive disease is something that can come and go and is not permanent like obstructive disease.

Kay Kreiss said the concern may be that a flavoring mix may cause restriction, not obstruction. As a researcher, she had an open mind as to whether there could be a flavor-related health outcome that is not bronchiolitis obliterans-like [i.e., not obstructive, but restrictive]. Setting up information handling for the NIOSH and FISHEP data has been a huge task. I am also concerned that some flavor companies may not be using the questionnaire.

Len Welsh asked for clarification on his question about if the group of 26 could include restrictive disease, obstructive disease and fixed and obstructive varieties.

Barbara Materna said that anything abnormal was being included in this group. The public document will note the restrictive disease risk; the wording to explain the different possible health outcomes is being worked on. Materna noted that not all 26 flavoring companies have done the first round of PFT, but the ones who haven't are very tiny companies with one or two exposed employees. DPH is working with FISHEP on a letter to tell these employers to arrange for the medical surveillance or face the possibility of a Cal/OSHA compliance inspection.

Jeremy Smith asked if there would be follow up medicals on all 26 instances of abnormal spirometry results. Materna said yes. Smith asked what the total flavor work force was; he thought he remembered 750. Materna thought it was more like 650.

Judi Freyman asked if employers were being directed to particular medical providers for their spirometry needs due to this concern about spirometry quality.

Barbara Materna said companies are free to choose any provider, but if asked we recommend UC Irvine. We have at least 10 providers being used. We monitor the quality as it comes in via Paul Enright's review and communicate any need for change.

Nancy Rachman asked at what point this data becomes public.

Barbara Materna said the data was not yet in a form suitable for dissemination, and further, since it was collected under the authority of the California Public Health Act it is not strictly public information. However, if certain information were redacted, it is possible that a requester could get the data.

John Hallagan asked if the 26 abnormal spirometry results were on the mild end or if there were any severe instances. Barbara Materna replied that generally the results were on the mild end, but three results are in the moderate range. All of the individuals are known by name. Hallagan asked if the DPH recommends that those employees with abnormal PFT be removed from exposures to flavorings. Len Welsh said this would be a medical decision decided on by a case be case basis. Barbara Materna said that the draft guidance document will discuss criteria for removal from exposure. Barbara Materna said there were 9 companies affected by abnormal PFT, and four with severe abnormalities. I think it will be a long time before there is enough data to know how low you would have to go to be safe, Materna said. John Hallagan asked if it had been possible to sample the areas at the 9 companies associated with PFT abnormalities. Len Welsh said that while such sampling had been performed it was still difficult to know how to interpret the results, given uncertainty with the NIOSH analytical method. Hallagan agreed it was a tough issue, especially with low rates of use, it gets complicated.

NIOSH REPORT: ANALYTICAL ISSUES

Lauralynn Taylor McKernan divided her NIOSH update into several segments. Further information about the topics she discussed can be found at www.cdc/NIOSH/Topic/Flavoring .
First she explained NIOSH had discovered problems with the sampling method it utilizes for diacetyl. This method was developed for the NIOSH investigation of respiratory illness in the microwave popcorn industry. Conditions in the flavoring industry are different, and NIOSH has determined that humidity causes underestimations of the dose. A team at NIOSH is currently trying to come up with a correction factor to account for reduced recovery of diacetyl due to humidity. NIOSH is also trying to establish a new laboratory method that will look like the OSHA method with modifications so sampling can be done for longer periods of time. To overcome recovery problems, NIOSH has

learned it is best to use larger collection tubes [200 to 400 mg] and maximize the air volume. Dr. Bob Stryker is the research chemist.

Barbara Materna asked what is the lowest level of detection. McKernan said this depends upon the sample volume. John Hallagan suggested NIOSH look at the analytical method for sampling glyoxol. Azita Mashayekhi asked whether diacetyl was sampled for as a vapor or a powder. McKernan said as a vapor.

John Hallagan said task based exposure analysis would be very interesting, noting that the flavor industry was very different from the popcorn industry. Exposures in flavor manufacturing may only be a few minutes over a day or days.

Fran Schreiberg asked someone to talk about the powder form. Will there be a report on that, she asked. McKernan said there was no plan for that, and that how diacetyl on powder might be inhaled remains unclear.

Kay Kreiss stated there had been no animal toxicology studies done looking at the relative toxicity of encapsulated or non-encapsulated diacetyl powders. There is an impression that plated powders have been associated with some of the worst illness instances in California. It appears engineering controls for powders may be more difficult and flavor companies have emphasized engineering controls to address liquids more than powders. Companies are even having difficulty finding good engineering advice. McKernan noted that there are designs in the ACGIH Ventilation Controls Manual for the control of powders.

NIOSH REPORT: ENGINEERING CONTROLS

McKernan next gave an update on NIOSH's engineering controls work. Three designs for control of liquid mixing are being tested in the NIOSH lab and are showing promise. The designs seem to offer good control for moderate cost with modest flow rates. NIOSH is now studying the effect of crossdrafts including from the activities of nearby workers. Next NIOSH will examine designs for engineering controls for bench top powder blending and powder packaging. Today, Kevin Dunn is evaluating the effectiveness of a mixing ventilation hood installed at a plant in California. Visualization of the effectiveness of the ventilation is being accomplished with smoke while tracer gas studies are being done to judge capture effectiveness. These engineering controls should safely remove all flavorings, not just diacetyl, from employees' breathing zones.

NIOSH REPORT: CONTINUING EVALUATION

Finally, Laurlynn Taylor McKernan reported that NIOSN continued to provide advice to flavoring companies and to evaluate data that has been collected in California. Azita Mashayekhi asked what chemicals have been sampled. McKernan said six aldehydes, three acids and several dusts. John Hallagan noted it was becoming standard to sample for these materials.

Len Welsh asked why this was so. Kay Kreiss said this was following FEMA's lead in the popcorn industry where diacetyl and acetone exposures where sampled for. Flavorings are vastly more complex, she said, and it was probably impossible for NIOSH or OSHA to develop a complete understanding. John Hallagan noted that the issue of dust is problematic. Kay Kreiss agreed that if you think of diacetyl on cornstarch dust entering the lungs, then you deliver a high dose in the lungs, with the tiny dust particles acting like little bomblets. Most abnormal PFT in California come out of powder applications, not liquid; anecdotally its coming out of powder. John Hallagan said he supported that idea on the possible mechanism for inhaled powders. Kay Kriess further described the liquid plating procedure in the flavoring manufacturing industry as opposed to encapsulated particles.

Julia Broyles asked why there should be a concern, since there was already a flour dust PEL. Len Welsh said that from a lowbrow regulator perspective, we should all think about minimizing dust; there are time-honored ways to do this. John Hallagan agreed there are areas that could be focused on for dust control.

Mark Scott elaborated on the microencapsulation process. Water, flavorings and starch are mixed and then sprayed. Spray drying is an enclosed process, so it is safer although any particles in the lungs would still be problematic.

Fran Schreiberg asked about the downstream users' exposure to dust when an employee drops a box of powdered flavor. Later in the meeting Len Welsh said he was not concerned with isolated, one time exposures from dropping a box; he was more concerned with the procedures and work practices of regular processing of flavors at downstream locations.

Nancy Rachman noted that for encapsulated flavors there was less risk of vaporization from this form of flavor powder but you still have to control the dust.

FEDERAL OSHA

Amanda Edens reported that Federal OSHA has established an emphasis program on diacetyl exposure. First popcorn facilities will be inspected and then flavoring manufacturers. She noted that respiratory protection requirements were operative even when there is no PEL for a hazardous substance, and that Federal OSHA also had available the possibility of issuing General Duty Clause [Section 5A1] citations during the emphasis program.
Len Welsh announced that Cal/OSHA would be meeting with Federal OSHA, NIOSH, CA DPH, and National Jewish Hospital to discuss putting all the sampling done by the various entities in one database.

Nancy Rachman asked about including private sector data. Len Welsh stated this could be done later and he noted that John Hallagan of FEMA had sent him some data. Nancy Rachman then asked Kay Kreiss for an update on information about diacetyl toxicology research, in particular about the effect of peak exposures.

Kay Kreiss said Ann Hubbs at NIOSH had done two dose rate studies on rates, including one on peak diacetyl exposures. This work should be published in the Fall. NIEHS is doing more extensive studies on both diacetyl and acetoin. Hubbs, meanwhile has gotten grant money to continue tests for three or four years on diacetyl as well as on other flavoring substances such as other aldehydes. The National Toxicology Program [NTP] has decided to evaluate diacetyl, acetoin and a third flavor ingredient; this evaluation will two to three years. John Hallagan said the third substance for the NTP study will be a butter flavor mixture that NTP is working with FEMA on selecting.

AFTER LUNCH

Discussion after lunch began with a review of the letter John Hallagan of FEMA had sent to Len Welsh. This letter contains a table listing generic flavor types and the percentage of diacetyl contained in these flavors when they are sent from the flavor manufacturer to the downstream food manufacturing concern. Hallagan pointed out that the concentration of diacetyl in the final food product will be far less than the concentration in the originally delivered flavor. There is a huge dilution factor and a huge processing loss, he explained. Most of the flavors on the list contained less than 1% diacetyl.

Nancy Rachman noted that historically microwave popcorn had utilized butter flavors containing 15%, 20% or even 30% diacetyl, while the table in the FEMA letter listed microwave popcorn with only 1 to 5% diacetyl.

Kay Kreiss asked what other substances are being used to replace the diacetyl.

John Hallagan said that indeed there had been some movement away from the use of diacetyl. One substitute was a trimer of diacetyl that had recently received the FDA's GRAS designation. Plating and encapsulation, the diacetyl trimer, all these things are tending towards greater stability—and there are more innovations on the way. But for some applications, diacetyl was still necessary. Meanwhile, substitution and innovation are being driven by regulation.

Jeremy Smith asked Nancy Rachman where she had gotten the popcorn diacetyl percentages from. John Hallagan said he could verify their accuracy. He noted in the past concentrations of flavorings were increased for the convenience of shipping.

Len Welsh asked Kay Kreiss if NIOSH had looked at the concentration of diacetyl in the popcorn investigations. She noted that the American Popcorn Board told NIOSH the concentration ranged from 1% to 20%, but that it was a trade secret. Our estimate was that the flavors we were interested in the popcorn industry were 10% and above.

Len Welsh asked Kay Kreiss if we should focus our regulation's scope on diacetyl concentration or on diacetyl quantity. She replied there was no clear data on which to base a decision. John Hallagan said that you can look at the flavor types and concentration ranges in comparison to pounds used. FEMA does a poundage survey

every five years. In the year 2000, 200,000 pounds of diacetyl was used. In 2005, much less. We can provide our poundage survey.

Len Welsh asked if there was something FISHEP could do to assist in data gathering. Dan Leiner said FISHEP had been getting better about asking employers about the quantity of flavor being used when FISHEP monitored.

Lauralynn McKernan questioned the value of such information, given that the type of work practice contributes so much to the eventual degree of exposure.

Len Welsh said we need to draw a line or else we'd be stuck with saying any facility that uses a diacetyl flavor would be covering. The precedent for using a certain percentage as a trigger is asbestos—0.1% for registration and 1% for the need for controls.

Kay Kreiss asked if we knew the distribution of spirometry abnormalities in relation to the annual use of diacetyl. Barbara Materna said we should ask the 26 FISHEP companies where their customers utilizing the highest diacetyl percentage flavors are. Len Welsh said he did not want to subpoena this information, especially since it probably only represented 5% of the California food manufacturing flavor market.

Juli Broyles said she was confused because at the last meeting we were talking about bifurcating the standard and looking at food manufacturing as data came in. Now we are talking about quantity versus percentage.

Len Welsh asked if we could predict exposure ranges from the diacetlyl percentages in flavors. Nancy Rachman said she didn't think you could unless you took into account the type of process involved. Welsh replied that that concept had been honored in the draft regulation by providing an exception for enclosed processes. We can either do this the rulemaking way, or the legislature will act.

Nancy Rachman suggested requiring monitoring by downstream users who utilized flavors with more than 5% diacetyl.

Judi Freyman said she agreed. The only downstream users to experience disease were the popcorn industry.

Kay Kreiss said that NIOSH was confident that mixers in the popcorn industry remained unsafe even after diacetyl percentages in the flavorings were reduced and process changes made. Even with very low exposures, NIOSH identified a case of lung disease.

Mark Scott said the flavors utilized by downstream users could be bulk analyzed without violating trade secrets. He said his company sold products with up to 3% diacetyl and no problems had been reported. These customers had had their insurance customers perform air monitoring and the result had been nothing detected. Len Welsh asked if he could reveal the names of these customers so DOSH could verify the lack of problems. Mark Scott said legally he could not.

Mike Horowitz reminded the body that at a previous meeting Kelly Howard had reported that FISHEP had documented significant short term exposures of 6 parts per million from a flavor with only 0.14% diacetyl. Mark Scott pointed out that that result was plating out of diacetyl at a ribbon mixer.

Juli Broyles asked if you could choose a percentage, what would it be? Len Welsh said Nancy Rachman had mentioned 5%; what did people think about that figure.

Rhonda Hrabchak said you couldn't compare until the sampling methodology problems had been cleaned up.

Nancy Rachman said her members had been basically following a decision tree. First they determined if they used a diacetyl containing flavor and if it was in liquid or powder or encapsulated form. Then they noted if the flavor was heated and if it was processed in an enclosure. After evaluation of these factors, if there was deemed to be a potential exposure risk, her members arranged for a third party assessment [air monitoring] or they instituted work practice or engineering controls to the lowest feasible level of exposure. If employee exposure was demonstrated, then the companies could possibly arrange for medical surveillance.

Fran Schreiberg said there still needs to be minimal training and a questionnaire to gauge for early symptoms. Self-reporting of shortness of breath could result in a smaller group of employees to watch.

Len Welsh asked Nancy Rachman if any of her members were doing medical screening. She said she was not sure, but in any case, no respiratory disease had been identified. Len asked her how important knowing the percentage of diacetyl in the flavorings was for her members to decide upon their actions. She replied that since 2000 her members had increasingly been taking steps to learn the percentage of diacetyl from their flavor suppliers.

Bob D'Amato stated his former flavor manufacturing client had very little employee exposure and hadn't known the risk. Maybe its like asbestos, and you don't know until you check. You are in a Pandora's box, Len. I hope you can get out of it.

Len Welsh asked Nancy Rachman what the trigger would be for screening in her assessment model. She replied that it was the opportunity for exposure verified with actual detected levels in air could trigger medical surveillance

Len Welsh asked what the Labor stakeholders thought about that idea.

Fran asked if that meant no coverage. Even a concentration of 1% could lead to exposure, she said.

Len Welsh said to Nancy Rachman that it sounds like GMA/FPA members think less about percentage and more about assessment. Some use flavorings with 5% diacetyl, but not many. So why not start with a low percentage of diacetyl? "What would be the downside?" he asked. Nancy Rachman replied that it depends upon what effect you want to have on the problem. You need to decide who you are trying to reach and the impacts on California, she said.

Len Welsh said the problem is we need information.

Jeremy Smith asked how food manufacturers would figure out they were using flavorings with 5% diacetyl. Mark Scott said the customers will ask their flavor suppliers if the flavorings they purchase have less than 2%, 3%, etc. Nancy Rachman stated that the flow of information from flavor manufacturers [formerly restrained] to their customers had changed. John Hallagan said the change had been dramatic in the last five to six months with state and national legislative activity plus insurance issues causing flavor manufacturers to be meet their customers' demands for flavoring content information.

Len Welsh said he was thinking now about a full regulation covering flavor manufacturing with a second part of the regulation for food manufacturers focusing on the generation and collection of information since the level of exposure is still speculative. If the goal is information gathering then the regulation should be geared to a low percentage as a trigger.

Fran Schreiberg said she was OK, maybe, with less of an enforcement approach possibly in this case, but others in Labor might not be supportive of the suggested approach having no engineering controls and no citations.

Len Welsh said to the contrary, there would be citations if things had been found by the food manufacturer's assessment and the employer had not corrected them. There is an assumption at the outset of the process that the employer would have to make an assessment; if they don't there could be a citation [for failing to assess.]

Fran Schreiberg said she still wanted medical surveillance and was still concerned about exposures from a dropped box of flavoring.

Len Welsh said he didn't think we had evidence that suggested there was a hazard from a single exposure like that.

Mark Scott said that information sharing would be facilitated by a regulation like the one being suggested; he felt a concentration of 5% would be a good trigger.

Len Welsh said he thought that was too high. Mark Scott said 3%. Len Welsh said if the goal is primarily to develop information, there should be a lower trigger.

Judi Freyman asked what information was trying to be developed. Nancy's decision tree, percentage concentration, quantity, ventilation, liquid, powder?

Len Welsh said to do the regulation we need to figure if there is a correlation of disease with percentage of diacetyl in flavorings. We want to try to get a handle on what types of airborne exposures lead to disease. If there were a huge problem in food manufacturing, somehow I think we would have seen some cases by now.

Kay Kreiss pointed out that the popcorn related illnesses went on for years without detection, and there had been a couple of examples in snack foods.

Len Welsh said we are seeing these illnesses now. Kay Kreiss said, yes, often when the individual is already a respiratory cripple. Len Welsh replied, fair enough, but one can say we haven't seen lots of those serious instances in food production.

Mark Scott said once there is a regulation on the books it will be easier to share medical information.

Nancy Rachman said the intent of the suggested information gathering regulation was admirable, but she didn't think it was realistic to think this information could be gathered before NIOSH makes its determination on a likely PEL.

Juli Broyles asked what would trigger medical surveillance.

Len Welsh said Nancy Rachman had said that if any exposure in food manufacturing is identified, then the medical monitoring is done, even now without a PEL. Nancy Rachman agreed her members look at medical surveillance if they find exposures, but most or all have not found any exposures.

Len Welsh said how about if [food] companies are required to assess the anticipated highest exposures and provide medical surveillance along with the concept of sampling their way out of the regulation's coverage.

DECISION TREE DISCUSSION

A version of the decision tree described earlier by Nancy Rachman was written on the whiteboard for discussion of its application as part of a regulation covering food manufacturing. If a product contained ____% diacetyl, employers would assess for exposure potential. If a process was totally enclosed, then there would be no further assessment even if the trigger percentage was present in a flavoring.

There was a discussion if heating to more than 100° should be a necessary requirement if or if process temperatures below this would obviate the need for further assessment. Diana Graham said that processes utilizing powdered flavorings without ventilation still posed a risk even if not heated.

Nancy Rachman said the decision tree was not just a yes/no question in regard to heated processes, ventilation, or closed enclosures, etc. The tree should be to help prioritize, not narrow the decision making to yes and no automatic answers.

Mary Ellen Hogan said that ventilation was not necessarily the equivalent of fully enclosed; if a process was indeed fully enclosed then there could be no further assessment. But ventilation alone was not necessarily exculpatory.

Len Welsh agreed, but he pointed out that there could be exposure when a fully enclosed process was opened. He agreed that heat could be a yes or a no factor in the decision making.

Kay Kreiss asked if you do medical screening but find nothing, can you screen out [of the regulation's coverage]? Len Welsh said this was a good question, and if so, after how many screenings, one, two?. Nancy Rachman asked if the DHS [DPH] guidance will address this. Barbara Materna said that right now the recommendations [for flavoring companies] is for an initial screening of exposed employees and every three months forever until we decide on a PEL. Len Welsh said we anticipate that most food companies will find very low exposures and will not need medical surveillance. The hard part will be when an employee is found with a PFT decline, he said.

John Hallagan saint that with the current litigation/insurance situation, the percentage trigger should be low. I'd advise any company using or making diacetyl [flavorings] to do assessments even at very low percentage levels—even if contract temporary employees are doing the work.

Juli Broyles asked if the decision tree could be sent out via email to get reaction before perhaps another meeting.

Len Welsh said he did not want another meeting but agreed with sending out the draft decision tree to seek reactions.

Bob D'Amato noted that 8CCR 5194 sets risk levels at 1% for non-carcinogens and 0.1% for carcinogens. Len Welsh replied that the Directors List differs as to what does have to be covered by 8CCR 5194. Diacetyl needs to be on the Directors List, and would therefore be covered.

Nancy Rachman recalled that Cal/OSHA had said it would develop a form for employers to utilize for assessment and certification of their plants. She was asked to clarify "certification." She said a third party certifying that exposures were low or that the identified exposure potential had been addressed with engineering controls in place.

The meeting ended with the agreement to send the draft decision tree, as modified by the discussion to the email list with two weeks available for comment, especially on three factors in the decision tree that were left undecided: 1) triggering % diacetyl in a

flavoring product; 2) frequency of medical surveillance in months if illness is found; and 3) frequency of medical surveillance in months if no illness has been found.

PROPOSED DECISION TREE

USES A FLAVORING PRODUCT WITH _____% DIACETYL?

↓ ↓

YES **NO: no further assessment**

↓

ENCLOSED PROCESS?

If **YES**=No opportunity for exposure: no further assessment

If **NO=**

3rd Party exposure assessment or employer certification

If **DETECTABLE EXPOSURE=MEDICALLY SCREEN EMPLOYEES [If no detectable exposure, no medical screening]**

↓

If **MEDICAL SCREENING DETECTS ILLNESS, RESCREEN EVERY _____ MONTHS**

If **MEDICAL SCREENING DETECTS NO ILLNESS, RESCREEN EVERY _____ MONTHS**